AUG 1 1 2011

UNISENSE® FERTILITECH

510(k) Summary – K111715

Administrative information:

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Date of summary: 24-July-2011

Propose of submission: Change in Indication for Use to allow device use for up to 5 days (120 hr) of culture. Device design has not been changed from the device cleared under K092183.

Device name:

Trade name	Common name	Device	Class	CFR Reference	Procode
EmbryoScope™ (Version D)	IVF Incubator	Assisted reproduction accessories	II	884.6120	85 MQG

EmbryoScope™ – (Version D):

Indication for Use: To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.

Device Description:

The EmbryoScope™ – (Version D) is an embryo incubator, which performs a series of unattended measurements including time-lapse microscopy at multiple planes and logging of incubation conditions on individual embryos during their development. The device has a build-in microscope within a red light source. Separate processing units control the incubation environment and the data acquisition to ensure safe and reliable operation. The Device allows incubation of up to 72 individual embryos in six sterile disposable EmbryoSlides™ each with capacity for 12 embryos.

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Table 1: Comparison of EmbryoScope™ - (Version D) K 092183 to EmbryoScope™ - (Version D) K 111715:

	EmbryoScope™ (Version D) K092183	**EmbryoScope™ (Version D) K111715**
Indication for use	To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to three days (72 hr) covering the time from post-fertilization to day 3 of development.	To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.
Discussion of Non-Clinical Tests performed for Determination of Substantial Equivalence	Underwent and passed electrical safety electromagnetic compatibility, environmental and operating performance testing. Classification according to IEC 60601-1.	Underwent and passed electrical safety electromagnetic compatibility, environmental and operating performance testing. Classification according to IEC 60601-1.

Summary: The differences between the EmbryoScope™ – (Version D) used for 5 days incubation do not alter the safety and effectiveness of the device. The EmbryoScope™ – (Version D) is similar, with respect to the FDA published predicate device description.

Clinical Testing:

Clinical data showed that the EmbryoScope™ – (Version D) performs according to the intended use of the device. No significant difference was found between the rates of ongoing pregnancies in the EmbryoScope™ – (Version D) with 5 days of incubation compared to three days of incubation. No adverse effects of image acquisition were observed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Dr. Mette Munch
QA Consultant
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DENMARK

AUG 1 1 2011

Re: K111715
Trade/Device Name: EmbryoScope™ - (Version D)
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: MQG
Dated: June 15, 2011
Received: June 20, 2011

Dear Dr. Munch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111715

Device Name: EmbryoScope™ – (Version D)

Indications For Use:

To provide an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111715